DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
New Orleans District
Nashville Branch
297 Plus Park Blvd.
Nashville, TN 37217

M3140A

11/9/99

November 9, 1999

CERTIFIED-RETURN RECEIPT REQUESTED

Crystal Mountain, Inc.
831 Blackburn Drive
Mobile, AL 36608

Gentlemen:

Ref: Warning Letter - 00-NSV-03

We have reviewed the label for your "Crystal Mountain" Premium Artesian Water packaged in 5 gallon plastic bottles, a sample of which was collected by FDA Investigator Cynthia R. Crocker on July 29, 1999. Our review found that this label causes the product to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101 - Food Labeling, as follows:

- The product is misbranded within the meaning of section 403(q)(1) of the Act because the product label includes the nutrition claim "SODIUM FREE," but fails to bear nutrition labeling as required by 21 CFR 101.9 and is not exempt from this requirement.

Final regulations promulgated under the Nutrition Labeling and Education Act of 1990, as published in the Federal Register, went into effect on May 8, 1994 except for those firms, which applied for and received an extension until August 8, 1994. Although you may have qualified for an exemption based upon your firm size and/or the amount produced, the inclusion of nutrition information on your labels ("SODIUM FREE") disqualifies you from any exemptions. These regulations require additional changes in your labels, including changes and additions to the nutrition labeling of your products. Any food products labeled after the effective date for these regulations must comply with the new labeling requirements. It is your responsibility to assure that the appropriate changes are made to your labels to bring your products into compliance with the law. We have enclosed a copy of 21 CFR 101 to assist you in this regard.

The above noted violation should not be misconstrued as an all-inclusive listing of deficiencies on your label. Other label violations could subject the product to legal action, and it remains your responsibility to assure that your product(s) are labeled in compliance with all applicable statutes enforced by the Food and Drug Administration.

Please notify this office in writing, within fifteen (15) days of the receipt of this letter, of the specific steps you have taken to correct the noted violation. If appropriate, please include a copy of your revised label. If you cannot complete your corrective action within fifteen (15) working days, state the reason(s) for delay and the time within which you expect to complete the corrections. Your response should be directed to Frank J. Jancarek, Compliance Officer, at the above letterhead address.

Sincerely,

James E. Gamet
Director, New Orleans District

JEG/kl

Enclosure: [21 CFR 101]